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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ryozo NAGAI et al.

Group Art Unit : 1614

Appl. No. : 10/511,274
(U.S. National Stage of PCT/JP03/05804)

Examiner : Brian Y.S. KWON

I.A. Filed : April 22, 2003

Confirmation No. : 6408

For : MEDICAMENT FOR THERAPEUTIC TREATMENT OF VASCULAR DISEASE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir :

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, the International Search Report, and the International Preliminary Examination Report issued in connection with International Patent Application No. PCT/JP03/05084, of which the present application is the U.S. National Stage Application. Copies of the International Search Report (in English and Japanese) and the International Preliminary Examination Report (in English) were enclosed with the papers when entering the U.S. National Stage on October 21, 2004. The Examiner is invited

to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein. The following is a list of the documents cited in the above-noted documents:

(1) SPORN et al., "*Proliferative Diseases*," The American Journal of Medicine, Vol. 70, pp. 1231-1236 (June 1981). Applicants note that this document is cited on page 1 of the specification of the present application;

(2) MIANO et al., "*Retinoids Versatile Biological Response Modifiers of Vascular Smooth Muscle Phenotype*," Circulation Research, pp. 355-362 (2000). Applicants note that this document is cited on page 1 of the specification of the present application;

(3) NEUVILLE et al., "*Retinoic Acid Regulates Arterial Smooth Muscle Cell Proliferation and Phenotypic Features In Vivo and In Vitro Through an RARα-Dependent Signaling Pathway*," Arterioscler Tromb. Vascular Biology, pp. 1430-1436 (1999). Applicants note that this document is cited on page 1 of the specification of the present application;

(4) JP 61-022047, together with an English language abstract of the same. Applicants note that this document is cited on page 4 of the specification of the present application;

(5) JP 61-076440, together with an English language abstract of the same. Applicants note that this document is cited on page 4 of the specification of the present application;

(6) KAGECHIKA et al., "*Retinobenzoic Acids. 1. Structure-Activity Relationships of Aromatic Amides with Retinoidal Activity*," Journal of

Medicinal Chemistry, Vol. 31, No. 11, pp. 2182-2192 (1988). Applicants note that this document is cited on page 4 of the specification of the present application;

(7) International Patent Publication No. WO 97/11061. Applicants note that this document is cited on page 5 of the specification of the present application;

(8) EYROLLES et al., "*Retinobenzoic Acids. 6. Retinoid Antagonists with a Heterocyclic Ring*," Journal of Medicinal Chemistry, Vol. 37, No. 10, pp. 1508-1517 (1994). Applicants note that this document is cited on page 5 of the specification of the present application;

(9) Japanese Patent Application No. HEI 7-255912 (Japanese Patent Publication No. HEI 09-100270), together with an English language abstract of the same. Applicants note that this document is cited on page 5 of the specification of the present application;

(10) HIATT et al., "*Drug-Eluting Stents for the Prevention of Restenosis: In Quest for the Holy Grail*," Catheterization and Cardiovascular Intervention, Vol. 55, pp. 409-417 (2002). Applicants note that this document is cited on page 9 of the specification of the present application;

(11) New England Journal of Medicine, Vol. 346, pp.1770-1771, and 1773-1780 (2002). Applicants note that this document is cited on page 9 of the specification of the present application;

(12) International Patent Publication No. WO 02/064065. Applicants note that this document is cited on page 9 of the specification of the present application;

(13) International Patent Publication No. WO 95/03036, together with patent family member U.S. Patent No. 5,886,026;

(14) International Patent Publication No. WO 00/10552;

(15) International Patent Publication No. WO 01/34132;

(16) HAXSEN et al., "*Retinoids Inhibit the Actions of Angiotensin II on Vascular Smooth Muscle Cells*," Circulation Research, Vol. 88, No. 6, pp. 637-644 (2001);

(17) MURAKAMI et al., "*Inhibition of Angiogenesis and Intrahepatic Growth of Colon Cancer by TAC-101*," Clinical Cancer Research, Vol. 5, No. 9, pp. 2304-2310 (1999);

(18) ZHOU et al., "*Retinoid-dependent pathways suppress myocardial cell hypertrophy*," Proceedings of the National Academy of Science of the United States of America, Vol. 92, No. 16, pp. 7391-7395 (1995);

(19) JP 2002-095756, together with an English language abstract of the same;

(20) JP 10-265381, together with an English language abstract of the same;

(21) STREB et al., "*Retinoids: Pleiotropic Agents of Therapy for Vascular Diseases?*," Current Drug Targets-Cardiovascular and Haematological Disorders, Vol. 3, No. 1, pp. 31-57 (2003);

(22) SHINDO et al., "*Krüppel-like zinc-finger transcription factor KLF5/BTEB2 is a target for angiotensin II signaling and an essential regulator of*

cardiovascular remodeling," Nature Medicine, Vol. 8, No. 8, pp. 856-863 (2002);

(23) JP 2002-320629, together with an English language abstract of the same;

(24) JP 2003-033439, together with an English language abstract of the same; and

(25) JP 2003-093520, together with an English language abstract of the same.

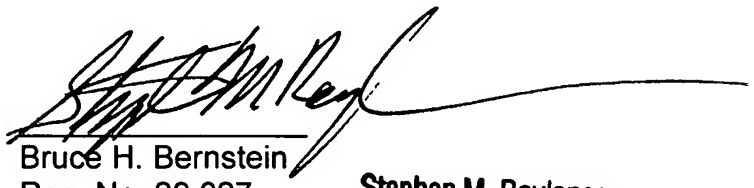
Further to 37 C.F.R. §1.98, copies of the U.S. patents are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Except for U.S. Patents, Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if an Office Action on the merits has issued and is crossing this statement in the mail, the undersigned hereby authorizes the Commissioner to charge any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
Ryozo NAGAI et al.



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FORM PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P26087	Application No. 10/511,274
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant Ryozo NAGAI et al.	
		Filing Date I.A. Filed April 22, 2003	Group 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5 8 8 6 0 2 6	03/23/99	HUNTER et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	61	- 0 2 2 0 4 7	01/30/86	JAPAN				
	61	- 0 7 6 4 4 0	04/18/86	JAPAN				
	9	7 / 1 1 0 6 1	03/27/97	W.I.P.O.				
	9	- 1 0 0 2 7 0	04/15/97	JAPAN				
	02	/ 0 6 4 0 6 5	08/22/02	W.I.P.O.				
	9	5 / 0 3 0 3 6	02/02/95	W.I.P.O.				
	0	0 / 1 0 5 5 2	03/02/00	W.I.P.O.				
	0	1 / 3 4 1 3 2	05/17/01	W.I.P.O.				
	2002	- 0 9 5 7 5 6	04/02/02	JAPAN				
	10	- 2 6 5 3 8 1	10/06/98	JAPAN				
	2002	- 3 2 0 6 2 9	11/05/02	JAPAN				
	2003	- 0 3 3 4 3 9	02/04/03	JAPAN				
	2003	- 0 9 3 5 2 0	04/02/03	JAPAN				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1	English Language Abstract of JP 61-022047.
	2	English Language Abstract of JP 61-076440
	3	English Language Abstract of JP 9-100270.
	4	English Language Abstract of JP 2002-095756.
	5	English Language Abstract of JP 10-265381.
	6	English Language Abstract of JP 2002-320629.
	7	English Language Abstract of JP 2003-033439.
	8	English Language Abstract of JP 2003-093520.
	9	SPORN et al., "*Proliferative Diseases*," The American Journal of Medicine, Vol. 70, pp. 1231-
		1236 (June 1981).
	10	MIANO et al., "*Retinoids Versatile Biological Response Modifiers of Vascular Smooth Muscle*
		Phenotype," Circulation Research, pp. 355-362 (2000).
	11	NEUVILLE et al., "*Retinoic Acid Regulates Arterial Smooth Muscle Cell Proliferation and*
		Phenotypic Features In Vivo and In Vitro Through an RARα-Dependent Signaling Pathway,"
		Arterioscler Tromb. Vascular Biology, pp. 1430-1436 (1999).

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P26087	Application No. 10/511,274
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	12	KAGECHIKA et al., "*Retinobenzoic Acids. 1. Structure-Activity Relationships of Aromatic Amides with Retinoidal Activity*," Journal of Medicinal Chemistry, Vol. 31, No. 11, pp. 2182-2192 (1988).
	13	EYROLLES et al., "*Retinobenzoic Acids. 6. Retinoid Antagonists with a Heterocyclic Ring*," Journal of Medicinal Chemistry, Vol. 37, No. 10, pp. 1508-1517 (1994).
	14	HIATT et al., "*Drug-Eluting Stents for the Prevention of Restenosis: In Quest for the Holy Grail*," Catheterization and Cardiovascular Intervention, Vol. 55, pp. 409-417 (2002).
	15	New England Journal of Medicine, Vol. 346, pp.1770-1771, and 1773-1780 (2002).
	16	HAXSEN et al., "*Retinoids Inhibit the Actions of Angiotensin II on Vascular Smooth Muscle Cells*," Circulation Research, Vol. 88, No. 6, pp. 637-644 (2001).
	17	MURAKAMI et al., "*Inhibition of Angiogenesis and Intrahepatic Growth of Colon Cancer by TAC-101*," Clinical Cancer Research, Vol. 5, No. 9, pp. 2304-2310 (1999).
	18	ZHOU et al., "*Retinoid-dependent pathways suppress myocardial cell hypertrophy*," Proceedings of the National Academy of Science of the United States of America, Vol. 92, No. 16, pp. 7391-7395 (1995).
	20	STREB et al., "*Retinoids: Pleiotropic Agents of Therapy for Vascular Diseases?*," Current Drug Targets-Cardiovascular and Haematological Disorders, Vol. 3, No. 1, pp. 31-57 (2003).
	21	SHINDO et al., "*Krüppel-like zinc-finger transcription factor KLF5/BTEB2 is a target for angiotensin II signaling and an essential regulator of cardiovascular remodeling*," Nature Medicine, Vol. 8, No. 8, pp. 856-863 (2002).

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